

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017–2018, 29 & 30 May 2017

Ref No: SQ17-000757

OUTCOME: 2 – Health Access and Support Services

Topic: P1024 and Nanomaterials

Type of Question: Written Question on Notice

Senator: Rice, Janet

Question:

- a) According to a paper published this year, a soluble nanomaterial, nano-hydroxyapatite can recrystallise in certain conditions.* It recrystallises in the same nano and needle-like form. Does FSANZ know if this is true of any other nanomaterial used in food?
- b) Will manufacturers be required to test for recrystallisation in ostensibly soluble nanomaterials?
- c) FSANZ was asked whether the definition in P1024 was used as a definition for purposes of responding to a manufacturer. Given that the definition was contained in the response to the manufacturer (doc 5 of documents released under Freedom of Information laws in July 2016), how can FSANZ claim it isn't using this definition?
*Schoepf, J. et al. (2017). Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. *NanoImpact* (5):22-28, p. 27

Answer:

- a) Schoepf et al 2017 speculated on the recrystallisation of hydroxyapatite under certain *in vivo* conditions, but did not provide useable supporting evidence. Food Standards Australia New Zealand (FSANZ) is unaware of evidence demonstrating nanoscale materials that are recrystallised *in vivo* that would be likely to change the conclusions around the safety of food additives used according to existing permissions in the *Australia New Zealand Food Standards Code*.
- b) The guidelines in the FSANZ *Application Handbook* require that an application for a new food additive must include detailed reports of all studies conducted in animals or humans to examine the toxicity and metabolic fate of the food additive and, if necessary, its degradation products or major metabolites. The need for individual studies addressing specific issues such as recrystallisation would need to be determined on a case-by-case basis.
- c) There is no legal definition for nanomaterial in Australia and New Zealand in relation to food. The status of Proposal P1024 has been addressed in the response to SQ17-000758. P1024 has not presented a definition for a nanoparticle. The statement contained in the abovementioned doc 5 refers to the fact that substances (nanomaterial or non-nanomaterial) present in foods in a completely dissolved form would be subject to a conventional chemical risk assessment process.